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Efficacy and Safety of Robotic Procedures Performed Using the da Vinci Robotic Surgical System at a Single Institute in Korea: Experience with 10000 Cases

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Purpose: To evaluate the efficacy and safety of robotic procedures performed using the da Vinci Robotic Surgical System at a single institute.

Materials and Methods: We analyzed all robotic procedures performed at Severance Hospital, Yonsei University Health System (Seoul, Korea). Reliability and mortality rates of the robotic surgeries were also investigated.

Results: From July 2005 to December 2013, 10267 da Vinci robotic procedures were performed in seven different departments by 47 surgeons at our institute. There were 5641 cases (54.9%) of general surgery, including endocrine (38.0%), upper (7.7%) and lower gastrointestinal tract (7.5%), hepato-biliary and pancreatic (1.2%), and pediatric (0.6%) surgeries. Urologic surgery (33.0%) was the second most common, followed by otorhinolaryngologic (7.0%), obstetric and gynecologic (3.2%), thoracic (1.5%), cardiac (0.3%), and neurosurgery (0.1%). Thyroid (40.8%) and prostate (27.4%) procedures accounted for more than half of all surgeries, followed by stomach (7.6%), colorectal (7.5%), kidney and ureter (5.1%), head and neck (4.0%), uterus (3.2%), thoracic (1.5%), and other (2.9%) surgeries. Most surgeries (94.5%) were performed for malignancies. General and urologic surgeries rapidly increased after 2005, whereas others increased slowly. Thyroid and prostate surgeries increased rapidly after 2007. Surgeries for benign conditions accounted for a small portion of all procedures, although the numbers thereof have been steadily increasing. System malfunctions and failures were reported in 185 (1.8%) cases. Mortality related to robotic surgery was observed for 12 (0.12%) cases.

Conclusion: Robotic surgeries have increased steadily at our institution. The da Vinci Robotic Surgical System is effective and safe for use during surgery.

Key Words: Robotic surgical procedure, efficacy, safety

INTRODUCTION

The da Vinci Robotic Surgical System (Intuitive Surgical, Moun-

tain View, CA, USA) was initially introduced for cardiac surgery in 1999, and it has been widely adapted for urologic, gynecologic, general, thoracic, and head and neck surgeries.¹⁻⁴ According to official statistics from Intuitive Surgical, approximately 2 million procedures were performed in 2013.⁵ Although long-term oncologic outcomes are generally lacking and robotic surgeries are more expensive than other surgeries, robotic technology is widely used in oncologic surgery, with demonstrated short-term advantages.⁴ Robotic surgery has overcome many limitations, including setup costs and surgical training. The tendency to shift from performing open surgery and laparoscopic surgery to robotic surgery seems to be inevitable worldwide.

Several studies have reported the efficacy and safety of robot-

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ic surgeries for various diseases, which have outcomes comparable to those of conventional or laparoscopic surgeries.^{2,3,6-15} However, to the best of our knowledge, no study has reported a comprehensive analysis based on the experience of multiple departments at a single institute. Since 2005, the Severance Hospital, Yonsei University Health System (Seoul, Korea) has been one of the largest centers in Asia that has adopted robotics in the surgical field,⁹ and several reports on this have been published.^{2,3,6-15}

This work reviewed the annual trends of various robotic surgeries performed in multiple departments and analyzed the efficacy and safety of robotic surgeries, including surgical incidence, outcomes, morbidity, mortality, and mechanical failures, at a single institute.

MATERIALS AND METHODS

Ethical considerations

The study was performed in agreement with the applicable laws and regulations, good clinical practices, and ethical principles described in the Declaration of Helsinki. The Institutional Review Board of Severance Hospital approved the study protocol (approval no. 1-2014-0023).

Data collection

All medical records of patients who underwent robotic surgeries between 2005 and 2013 at Severance Hospital, Yonsei University Health System were searched for and reviewed. Detailed statistical data regarding the patients and surgeries were provided by the Robot and Minimal Invasive Surgery Center of Severance Hospital. All surgeries were performed according to the standard protocol of robotic surgeries provided by each department of our institute. Final analyses were performed after manual sorting of all records and confirmation of consistency of the lists of patients from the Robot and Minimal Invasive Surgery Center and the patient cohort from the electronic medical recording system of Severance Hospital.

Comparative data regarding cases in Korea and the rest of the world were obtained from the database of the Ministry of Health and Welfare, Republic of Korea and from Intuitive Surgical. Demographical data were obtained from the official records of the Statistics Korea in 2014.

Statistical analysis

All robotics procedures were classified into groups by year according to diagnosis, department, organ, and surgeon. Subsequently, statistical analyses and comparisons were performed for the procedures at Severance Hospital, other domestic procedures, and robotic procedures elsewhere worldwide. To evaluate the reliability of the robotic system during various surgical procedures, additional analysis was performed regarding the incidence and type of perioperative malfunctions,

failure of the da Vinci Surgical System (Intuitive Surgical) during procedures, and their consequences. Mortality related to robotic surgery was also reported according to the year of occurrence.

RESULTS

Introduction and use of the da Vinci Surgical System at Severance Hospital

Our institute initially introduced one standard da Vinci Surgical System (Intuitive Surgical) in May 2005 and started robotic surgery in July 2005. In June 2006, a new da Vinci S System (Intuitive Surgical) replaced the existing standard system. The second and third da Vinci S systems (Intuitive Surgical) were introduced in June 2006 and January 2008. In January 2010, the fourth da Vinci Si System (Intuitive Surgical) was introduced for a total of four robotic systems. Between July 2005 and December 2013, the robotic surgery system was used for a total of 10267 cases.

Although robotic surgery at Severance Hospital was started with only six surgeons from three different departments (general surgery, urology, thoracic surgery) in 2005, more than 40 surgeons from seven departments, including obstetrics and gynecology, otorhinolaryngology, cardiac surgery, and neurosurgery, perform robotic surgeries at present. A statistical analysis of the number of procedures performed by each surgeon revealed that 15 surgeons performed 93.47% of all 10000 surgeries. One surgeon performed more than 2500 surgeries, two surgeons performed more than 1400 surgeries each, two surgeons performed more than 500 surgeries each, and 10 surgeons performed more than 100 surgeries each.

The Minimal Invasive Surgery Center of the Severance Hospital is in charge of all business affairs related to robotic systems and is responsible for gathering statistical and clinical data regarding robotic surgeries conducted at Severance Hospital.

Analysis of annual robotic surgeries at Severance Hospital

Table 1 shows the annual reports of the numbers of robotic procedures. Fig. 1 shows the cumulative numbers per department, per organ procedures, and in total for the period between 2005 and 2013 at Severance Hospital. Since robotic surgery first began in 2005, there has been a constant increase in the number of procedures. The cumulative procedures performed at a single center were 1000 and 5000 in 2008 and 2010, respectively. The cumulative number of da Vinci procedures reached 10000 in November 2013. The total annual number of procedures in 2008, when the third robotic system was introduced, was 1000. The total annual numbers of procedures were 1600 in 2009, 1700 in 2010, and 1800 in 2012. From 2009 to 2013, more than 1500 procedures were performed each year.

Table 1. Number of Robotic Procedures Using the da Vinci Surgical System (Intuitive Surgical) according to Department and Organs at Yonsei University Severance Hospital

	2005	2006	2007	2008	2009	2010	2011	2012	2013	Total	%
By department											
GS	11	55	197	588	967	1053	820	990	960	5641	54.9
Endocrine	0	0	50	341	735	716	594	760	703	3899	38.0
Upper GI tract	8	43	74	97	96	134	80	113	142	787	7.7
Lower GI tract	0	10	66	120	115	174	122	87	74	770	7.5
HBP	3	2	7	28	21	26	7	9	19	122	1.2
Pediatric	0	0	0	2	0	3	17	21	22	65	0.6
URO	12	98	230	434	566	504	452	545	551	3392	33.0
OBGY	0	18	22	41	52	67	51	44	32	326	3.2
ENT	0	0	0	15	28	93	193	205	187	721	7.0
TS	1	7	18	10	2	11	26	33	41	149	1.5
CS	0	6	11	8	3	1	1	0	0	30	0.3
NS	0	0	0	0	1	4	1	1	0	7	0.1
Total	24	184	478	1096	1621	1733	1544	1818	1771	10267	100.0
By organ											
Thyroid	0	0	50	338	731	752	696	846	771	4184	40.8
Prostate	11	96	207	350	448	408	393	444	459	2816	27.4
Stomach	8	43	74	97	96	134	80	113	139	784	7.6
Colorectal	0	10	67	121	115	175	122	87	73	770	7.5
Kidney/ureter	1	2	18	75	107	86	57	93	88	527	5.1
Head and neck	0	0	0	15	26	51	89	118	113	412	4.0
Uterus	0	18	22	41	52	67	51	44	34	329	3.2
Thoracic	1	7	18	10	2	11	26	33	41	149	1.5
Other	3	8	23	49	42	49	30	40	52	296	2.9
Total	24	184	479	1096	1619	1733	1544	1818	1770	10267	100.0

CS, cardiac surgery; GI, gastrointestinal; GS, general surgery; HBP, hepatobiliary; ENT, ear/nose/throat; NS, neurosurgery; OBGY, obstetrics and gynecology; TS, thoracic surgery; URO, urology.

The department with the highest number of robotic procedures was general surgery (54.9%), which is much higher than the numbers of other departments, such as urology (33.0%), otorhinolaryngology (7.0%), and obstetrics and gynecology (3.2%). The yearly analysis showed that urology had the highest number of procedures from 2005 to 2007. However, from 2007 to 2008, general surgery procedures rapidly increased, and it had the highest number of procedures until 2013. Urology procedures increased every year until 2009; after that time, the number has remained stable. The frequency of otorhinolaryngology procedures rapidly increased after 2010. Moreover, the numbers of procedures performed in the obstetrics and gynecology department and other departments have decreased and have shown no signs of increasing.

Analysis of annual robotic surgery according to organ

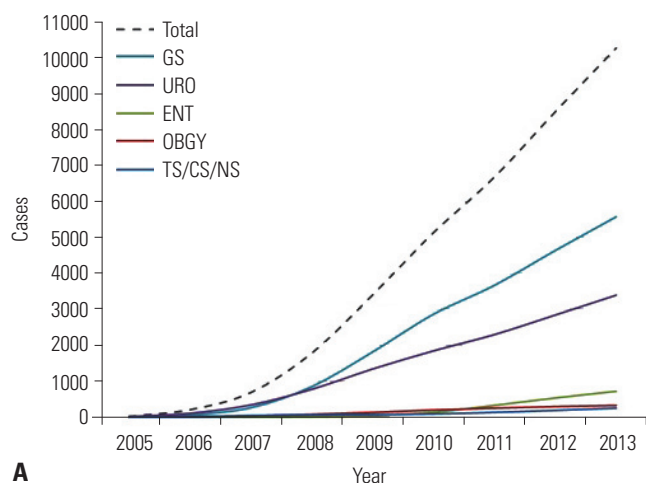
Table 1 and Fig. 1B show the number of annual procedures according to the operated organs. Most surgeries were performed for the thyroid (40.8%) and prostate (27.4%) glands; these two organs accounted for more than half of all procedures. Other prominent areas included the stomach (7.6%), colon and rectum (7.5%), kidney (5.1%), head and neck (4.0%), uterus (3.2%),

thorax (1.5%), and others (2.9%).

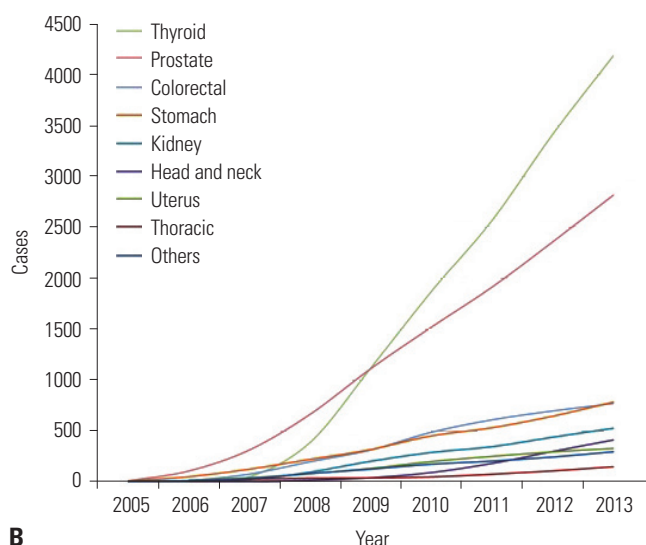
The results analyzed according to year revealed trends similar to those seen after the analysis performed according to department. Thyroid surgeries showed an increase similar to that seen for the annual trend in general surgery. Thyroid procedures were first performed at our hospital in 2007. Although they began slightly later than prostate surgeries, a drastic increase was seen in 2008. From 2008 until 2013, thyroid procedures comprised the majority of procedures. 92.7% of thyroid procedures are performed in the general surgery department; among all procedures in the general surgery department, thyroid procedures have the highest percentage (69.6%). Prostate procedures are only performed in the urology department (83.2%); therefore, the annual trend of prostate procedures is very similar to that of annual urology procedures. In contrast, procedures on the colon and rectum, stomach, kidney, head and neck, and uterus have remained constant, and no apparent growth trend was observed.

Analysis of robotic surgery for malignant and non-malignant disease

We compared statistics related to robotic surgery for malig-

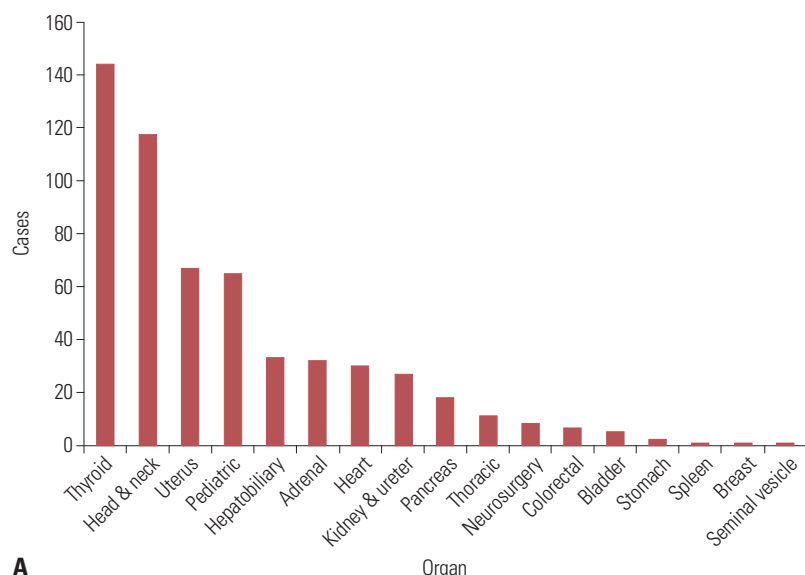


A

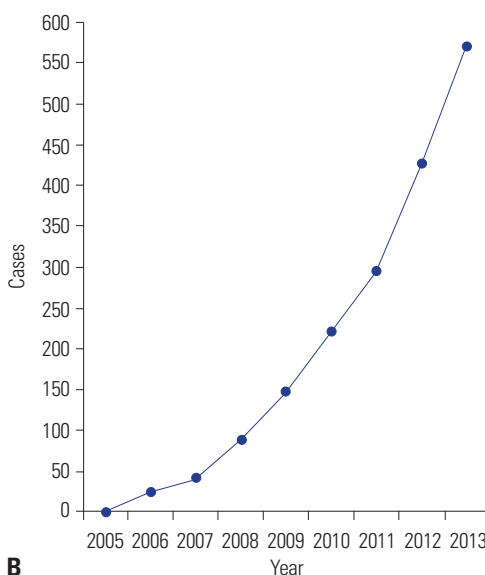


B

Fig. 1. Cumulative number and annual number of robotic procedures according to departments (A) and organs (B) at the Severance Hospital.



A



B

Fig. 2. Number of robotic procedures according to organs (A) and cumulative number of procedures (B) for benign disease.

nant and non-malignant diseases (Fig. 2). Procedures for malignant disease comprised the majority (94.5%) of all robotic procedures. However, only 569 procedures were performed for non-malignant diseases. Of these, the proportion of thyroid surgeries was highest (144), followed by head and neck (117), uterus (67), pediatric (65), hepatobiliary (33), adrenal (32), heart (30), kidney/ureter (27), pancreas (18), thoracic (11), and other (25) surgeries. All cardiac, adrenal, spleen, neurosurgery, and pediatric surgeries were performed for non-malignant diseases. Although the number of surgeries was still very low, compared to those for malignant diseases, robotic surgeries for benign diseases are constantly increasing.

Reliability and safety of robotic surgery

Although robotic surgery has many advantages over other surgical approaches, many studies have reported that mechanical failure and malfunction can occur because of its complexities.¹⁶⁻¹⁹ According to previous reports, the rate of malfunction and mechanical failure of robotic systems at Severance Hospital was approximately 2.4% from 2005 to 2008.^{18,19} However, among the 10267 procedures that we analyzed, mechanical failure was observed for only 1.8%. Most of these were related to instrumental problems; however, because this was easily solved by replacing the malfunctioning instrument, no cases of malfunction led to conversion to open or laparoscopic surgery (Table 2). There were only seven cases of malfunction of the

Table 2. Mechanical Failure and Malfunction of Robotic Surgery Using the da Vinci Surgical System (Intuitive Surgical)

Type of mechanical failure and malfunction	Cases (%)
Mechanical failure and malfunction	32 (17.3)
System error	23 (12.4)
Instrument error	130 (70.3)
Total	185 (100)

Table 3. Number of Mortality Cases for Robotic Procedures Using the da Vinci Surgical System (Intuitive Surgical)

Year	2005	2006	2007	2008	2009	2010	2011	2012	2013	Total
Procedures (n)	24	184	479	1096	1619	1733	1544	1818	1770	10267
Robotic surgery-related mortality (n)	0	0	1	3	1	1	1	3	2	12
Mortality rate (%)	0.00	0.00	0.21	0.27	0.06	0.06	0.06	0.17	0.11	0.12

robotic system that directly caused conversion to another approach: three cases were converted to laparoscopic surgery and four were converted to open surgery. After 2008, despite significant increases in the number of procedures, the numbers of malfunctions and failures have not increased significantly. This is mostly because the da Vinci system (Intuitive Surgical) has improved, and the experience level of surgeons has increased. Furthermore, because a total of four robotic systems are being used, a malfunctioning one can be replaced with another.¹⁹

Robotic surgery-related mortality among 10267 cases was also evaluated. During the entire analysis period, only 12 cases (0.12%) were reported (Table 3).

DISCUSSION

Minimally invasive surgery and robotic surgery have developed considerably in the past two decades. Robotic surgery presents advantages similar to those of minimally invasive surgery, such as less postoperative pain, shorter hospital stay, quicker recovery, and smaller wounds. In addition, robotic surgery allows a three-dimensional magnified view of the surgical field, enables intuitive movements, eliminates hand tremors, and provides a larger range of motion, all of which provide significant advantages for surgeries performed in limited and confined spaces.²⁰ These advantages are primarily observed for surgeries performed in the obstetrics and gynecology, urology, and general surgery departments.

Although the majority of robotic surgeries have been performed in the United States, their incidence is increasing in other countries, including Korea. According to the official statistical data provided by Intuitive Surgical in 2014, a total of 2965 da Vinci Surgical Systems (Intuitive Surgical) are in use in 55 countries, and 2083 systems are being used in the United States. In Asia, a total of 288 da Vinci Surgical Systems (Intuitive Surgical) are in use across 10 countries, including 43 systems in Korea. Singapore has the highest proportion of robots per million population (1.27/million population), followed by Japan (1.25/million population) and Korea (0.85/million population).^{5,21-23} This indicates that robotic surgery has been rapidly increasing in Korea over the past 10 years.

According to data regarding annual worldwide procedures provided by Intuitive Surgical,⁵ gynecologic and urologic surgeries are rapidly increasing. Since 2006, gynecologic procedures have been constantly increasing, thereby comprising more than half of all robotic surgeries performed in 2010. How-

ever, according to the Korean Central Cancer Registry, which recorded the annual percentage of malignant diseases from 1999 to 2011, the incidence of thyroid cancer was 23.3%, that of prostate cancer was 13.8%, and that of colorectal cancer was 5.6% per 0.1 million population, which differ from global data.²⁴ This implies a difference in the number of robotic surgeries at Severance Hospital and that reported by global statistics. Therefore, further statistical analyses are needed to explain this.

Thyroidectomy comprises a large portion of robotic surgeries at Severance Hospital, contrary to the global trend. The first robot-assisted thyroidectomy was performed in 2007. The numbers rapidly increased within 1 year and are still increasing (Fig. 1B). Thyroidectomy is most frequently performed in the general surgery department at Severance Hospital. However, thyroidectomy is also performed in the otorhinolaryngology department, which also explains the constant increase in robotic surgeries. Although urologic and gynecologic surgeries comprise the majority of robot-assisted procedures globally, thyroidectomy performed by the general surgery team is the most frequent robot-assisted surgery at Severance Hospital. According to the Korean Central Cancer Registry, the incidence rate of thyroid cancer per 0.1 million population increased by 23.3% from 1999 to 2011.²⁴ Endoscopic thyroidectomy was performed before robotic thyroidectomy, and it had limitations of restricted vision, difficulty with instrument handling, and lack of tactile perception.²⁵ More than 650 cases were performed via endoscopic surgeries from 2001. Since 2007, when the robotic system was introduced, the number of robotic thyroidectomies has increased. Our institution was a pioneer of robotic thyroidectomy in Korea. On the basis of the development and accumulated experience of many surgical methods, we extended the indication for the robotic system to more advanced cases.^{26,27} Current studies have reported surgical outcomes comparable to those of conventional procedures.^{28,29}

Robot-assisted prostatectomy was the first robot-assisted surgery performed in Korea. The proportion of cases thereof has constantly increased, and the increase is similar to global trends. Since the da Vinci surgical system was introduced at Severance Hospital, robot-assisted prostatectomy has been performed not only for localized prostate cancer but also for locally advanced prostate cancer.^{10,14,30-33} Among all prostatectomy cases, 28% were performed for patients with locally advanced prostate cancer. Currently, active surveillance or focal therapy is recommended for patients with low-risk prostate cancer in Korea^{34,35}; however, surgery is still the main treatment. In addition, robot-assisted prostatectomy is performed not only for high-risk patients but also for very high-risk patients

with cancer stage beyond T3b or with bone metastasis; this trend is expected to persist at our institution.^{36,37}

The proportion of gynecology cases in Korea is much lower than that seen globally. Although the number of cases of robot-assisted gynecologic procedures is constantly increasing, it is limited to malignancies, such as cervical cancer. Cervical cancer is the second most common malignancy in women globally, and regardless of geographical distribution, it is still a major cause of morbidity and mortality. However, the incidence rate of cervical cancer in developing countries has been decreasing steadily over the past few decades due to early detection, treatment, and vaccination.^{38,39} In Korea, the incidence of cervical cancer has been decreasing annually by 3.9% per 0.1 million population.²⁴

At our institution, compared to non-malignant diseases, most malignancies were treated with robotic surgery. Debates regarding surgical results and differences in treating benign diseases with the traditional laparoscopic approach and robot-assisted surgery still exist. Robotic surgery for benign disease is not covered by the private insurance system in Korea, which is an obstacle. However, indications for robotic surgery for non-malignant gynecologic conditions, such as uterine myoma, are increasing. Despite the lack of evidence and high costs, robot-assisted surgery for non-malignant conditions is increasing because it provides several advantages in limited working fields, such as intracorporeal suturing, pediatric patients, patients with small pelvises, cardiac surgery, and head and neck surgery.⁴⁰ Along with the accumulation of experience and improvement in cost-effectiveness, robotic surgery for non-malignant disease is expected to generate competition in the field of surgery. Therefore, the role of robotic surgery in the gynecologic field is expected to grow.

Robotic systems involve very complex instruments with mutual organic unification. Malfunction or mechanical failure in the robotic system could lead to serious perioperative problems. The largest study to evaluate the malfunction risk when using robotic systems in general surgery reported a malfunction incidence of 3.4%, although the rate of conversion to open surgery was only 0.2%.⁴¹ Except for problems with instruments, the system failure rate was only 1.7%, and no mortality and morbidity related to robotic dysfunctions were reported. According to the United States Food and Drug Administration database, only 168 cases of malfunction were reported for more than 50000 cases during 8 years of robotic surgery.⁴² Among 1797 robotic surgery cases at our institution,¹⁸ malfunction was reported for 2.4% (43) cases; among these cases, 44.2% (19) were due to instrument error. In this study, the malfunction rate decreased to 1.7% since 2009; the overall malfunction rate was 1.8% among 10000 cases; and the rate of conversion was very low. All cases involving malfunction and failure were handled intraoperatively without stopping the surgery. Robotic surgery-related mortality was defined as conversion to open surgery and death of the patient. Since 2005, there have

been no deaths, and 0.12% (12) of cases required conversion to open surgery for reasons, such as major vessel injury (three cases) or severe adhesion (nine cases). Previously published studies have reported a 2% open/radical conversion rate for robotic partial nephrectomy and a 1.1% conversion rate for robotic surgery for gynecology.^{43,44}

The incidence of robotic procedures in Korea has grown dramatically in the past decade as the incidence of cancer continues to increase. Moreover, approximately 33% of all robotic systems in Asian countries are in Korea, which has the second-highest number of robotic systems in a single Asian country.^{5,45}

This study had several limitations. First, this was a retrospective review based on medical records. Second, this study was not a comparative study, and a descriptive analysis of data could not prove superiority to other methods. Finally, the data analysis at a single institution did not reflect or represent global trends. Despite these limitations, our study analyzed robotic surgery for 10000 cases of various diseases in seven different departments of a single institution.

In conclusion, at our institute, increases in the incidence of robotic surgeries were similar to worldwide trends. However, there were characteristic differences in the incidences of thyroid and obstetric surgeries between 2005 and 2013. Our experience, based on 10267 robotic surgeries performed at our hospital, indicates that the system has high reliability and a low incidence of malfunction, failure, and mortality. Therefore, robotic surgery can be considered a safe alternative to conventional surgery.

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